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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,037	10/27/2003	Cynthia T. Clague	P-11210.00	3891
27581	7590	04/24/2008		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			04/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/694,037	Applicant(s) CLAGUE ET AL.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 7-14, 24-31 and 35-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15-24 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-46 are pending in this present application.
2. In previous Office action, claims 1-6, 15-24 and 32 were examined and rejected and claims 7-14, 24-31 and 35-46 have been withdrawn from further consideration.

Response to Amendment

3. Applicant's arguments with respect to claims 1 and 18 have been fully considered but they are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 1-3 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro (U.S. 5,314,440) in view of Irisawa (JP 2003-210473).**
7. Regarding claims **1 and 18**, Shapiro discloses a vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising: an elongated instrument shaft (12) extending between a shaft proximal end and a shaft distal end (fig. 1) and having an instrument shaft axis (longitudinal axis) the elongated instrument shaft comprising a fixed or first shaft member (60) and a movable or second shaft member (62) adapted to move with respect to the fixed shaft member in the direction of the instrument shaft axis (col.4, lines 8-38); a first or fixed cutting blade (70) fixed to the first or fixed shaft member (60) at the shaft distal end to extend substantially laterally to the instrument shaft axis to a first or fixed cutting blade free end, the first or fixed cutting blade (70) having a blunt distal leading blade side (rounded distal side of 70), a proximal, trailing side having a first or fixed cutting edge (72), and a cutting tip (sharp pointed tip of 72) at the fixed cutting blade free end; a second or movable cutting blade (74) having a distal, leading edge (76) fixed to the second or movable shaft member (62) at the shaft distal end (68), the second or movable cutting blade extending substantially laterally to the shaft axis and

having a second or movable cutting edge along the second or movable cutting blade distal, leading edge (fig.2); means for maintaining the second or movable shaft member in a retracted position with the second or movable cutting blade spaced proximally from the first or fixed cutting member (fig. 2); and means (20) for moving the movable shaft member with respect to the fixed shaft member (60) between the retracted position separating the fixed and movable cutting edges (fig.2) and an extended position wherein the first and second or fixed and movable cutting edges are substantially in side-by-side alignment to shear the vessel wall and form a slit therein (fig.3).

8. Still regarding claims **1 and 18**, Shapiro discloses the invention substantially as claimed except for the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side. However, Irisawa discloses such a feature. Figures 11-16 of Irisawa's drawings disclose a fixed cutting blade having a fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side. Since it has been held the simple substitution of one known element for another to obtain predictable results is old and well known in the art therefore it would have been

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obvious to modify the fixed cutting blade of Shapiro according the suggestion of Irisawa.

9. The statement of intended use: "as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel" has been carefully considered but deemed not to impose an structural limitations on the apparatus claims. The device of Shapiro is capable of being used as claimed if one desired to do so.
10. Regarding **claims 2 and 19**, the first or fixed cutting blade (70) is disposed to extend laterally to the shaft axis by a shank (66) having a shank proximal end mounted to the first or fixed shaft member (60) at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the movable cutting blade to a shank distal end (fig. 2); and the first or fixed cutting blade (70) extends laterally to the shaft axis from the shank (66) distal end to the fixed cutting blade free end and has a substantially straight fixed cutting edge (fig. 2).
11. The statement of intended use: "whereby the cutting tip at the fixed cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen

- of the body vessel" is capable of being performed by the device of Shapiro and once again not given any weight in the absence of any structural limitations.
12. Regarding **claims 3 and 20**, the means for maintaining the first and second shaft members in a retracted position (fig. 2) comprises a spring (48) mounted between the first and second or fixed and movable shaft member and exerting retraction force there between (col.3, lines 22-25); and the moving means comprises means for transmitting force overcoming the retraction force to the second or movable shaft member to move the movable shaft member with respect to the first or fixed shaft member between the retracted position and the extended position (figs. 2 & 3; co1.4, lines 23-45).
13. **Claims 4-6, 15-17, 21-23 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro in view of Irisawa as applied to claims 1 and 18 above and further in view of Taylor et al (US 6,036,641).**
14. Shapiro discloses the invention substantially as claimed above, but fails to disclose stabilization means in combination with the vessel wall cutting instrument. However, Taylor teaches various stabilization means including a means for suction (co1.16, lines 18-21), an occlusion frame (figs. 10C and 36), and a means to apply compressive force (fig. 37A; co1.29, lines 40-50). Apparently the advantage of the stabilization means as taught by Taylor is for beating heart coronary artery bypass graft procedure (CABG). Therefore, it would have been obvious to a person of ordinary skill in the art to further utilizing the device of Shapiro by incorporate the stabilizing means as taught by Taylor so that it too would have the advantage.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731